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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,906	02/22/2002	Setsuko Ueda	F-7333	5913

28107 7590 04/04/2003
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EXAMINER

BADIO, BARBARA P

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 04/04/2003

5

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/069,906

Applicant(s)

UEDA ET AL.

Examiner

Barbara P. Badio, Ph.D.

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

First Office Action on the Merits

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The language of the instant claims creates confusion as to the claimed invention for the following reasons:

Claim 1 recites a component (A) wherein B is an alcohol residue and a phenol compound (B). Is the alcohol residue B of component (A) the same as the phenol compound (B)? The present specification discloses said alcohol residue of component (A) differs from the phenol compound (B). However, claim 6 recites a phenol compound (A) which would imply said component (A) might be similar to said phenol compound (B). For the purpose of art rejection, it is assumed claim 6 should read "phenol compound (B)".

Claim 3 recites the phrase "said component (A) is a block polymer of ethylene oxide *or propylene oxide*". Claim 1 does not encompass block polymer of only propylene oxide because the formula of component (A) indicates the presence of a polymer of ethylene oxide, $-(CH_2CH_2O)_{\geq 4}$.

Claim 6 also recites "a member selected from the group consisting of a phenol and a resorcinol". By the use of "a" does applicant intends any compound having a phenol or resorcinol moiety" or "a member selected from the group consisting of phenol or resorcinol"? For the purpose of art rejection, the examiner assumes applicant intends the latter.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-5 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Tamarkin ('669).

Tamarkin teach compositions useful in treating dermatological disorders comprising α,ω -dicarboxylic acids such as di(ethyl salicylate)azelate and polyethylene glycol (see the entire article, especially col. 4, lines 11-67; col. 6, lines 18-52; col. 8, line 63 – col. 9, line 35). The reference teaches use of 0.1%-30% of the α,ω -dicarboxylic acids (see col. 9, lines 18-35). The reference exemplifies lotions containing 10 and 20% di(ethyl salicylate)azelate (see Examples 5-11). The compositions taught by the reference are encompassed by the instant claims.

5. Claims 1-5 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Reeve et al. (EP 196,632).

Reeve et al. teach compositions for transdermal drug delivery comprising a mixture of organic polysaccharide, polyethylene glycol and a hydroxybenzoic acid (see the entire article, especially page 3, lines 22-28). The reference teaches various amounts of salicylic acid (see page 5, lines 17-24, page 6, lines 10-14). The reference exemplifies gels containing 15, 25 and 35% salicylic acid (see Examples 1-3, 5 and 6). The compositions taught by the reference are encompassed by the instant claims.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reeve et al. (EP 196,632) and Tamarkin ('669) in combination.

Reeve et al. teach compositions for transdermal drug delivery comprising a mixture of organic polysaccharide, polyethylene glycol and a hydroxybenzoic acid (see the entire article, especially page 3, lines 22-28). The reference teaches various amounts of salicylic acid (see page 5, lines 17-24, page 6, lines 10-14). The reference exemplifies gels containing 15, 25 and 35% salicylic acid (see Examples 1-3, 5 and 6).

Tamarkin teach compositions useful in treating dermatological disorders comprising α,ω -dicarboxylic acids such as di(ethyl salicylate)azelate and polyethylene glycol (see the entire article, especially col. 4, lines 11-67; col. 6, lines 18-52; col. 8, line 63 – col. 9, line 35). The reference teaches use of 0.1%-30% of the α,ω -dicarboxylic acids (see col. 9, lines 18-35). The reference exemplifies lotions containing 10 and 20% di(ethyl salicylate)azelate (see Examples 5-11).

The instant claims differ from the reference by reciting phenolic compounds not exemplified by the references. However, phenolic compounds such as salicylic acid and resorcinol are known anti-acne/keratolytic agents (see Tamarkin, '669, col. 5, line 57 – col. 6, line 27). Thus, it would have been obvious to the skilled artisan in the art at the time of the invention to substitute any anti-acne/keratolytic agent in the prior art compositions taught by Reeve or Tamarkin with the reasonable expectation of obtaining a composition having properties as taught by the prior art. The motivation would be based on the desire to formulate other anti-acne/keratolytic agents in the compositions as taught by Reeve or Tamarkin in order to obtain additional compositions having dermatological effect as taught by the prior art.

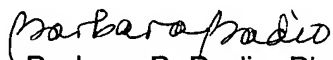
Telephone Inquiry

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 703-308-4595. The examiner can normally be reached on M-F from 7:30am-4pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1616

BB
April 2, 2003